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OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

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Glyphosate. Amended Residential Exposure Assessment for a Registration

Review.

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Introduction

The Office of Pesticide Programs (OPP) HED assesses the risks posed to humans from exposure to pesticide chemicals. The PRD of OPP asked HED to evaluate hazard and exposure data and conduct dietary, occupational, residential, and aggregate exposure assessments, as needed, to estimate the risk to human health that will result from all registered uses for glyphosate (N-(phosphonomethyl)glycine) in support of Registration Review. The incidental oral endpoint was recently updated from 175 mg/kg/day to 100 mg/kg/day. The existing glyphosate residential uses were previously assessed in October 2012 (D398862). This memorandum only reevaluates the residential exposure especially the incidental oral exposure using the updated incidental oral endpoints, 2012 Residential Standard Operating Procedures (SOPs) and the draft aquatic SOP (November 2015). An aggregate human risk assessment for registration review is presented in a separate Health Effects Division (HED) memorandum (see M. Perron et al., D417700, 2017).

It is HED policy to use the best available data to assess exposure. Sources of generic data, used as surrogate data in the absence of chemical-specific data, include the Pesticide Handlers Exposure Database Version 1.1 (PHED 1.1); the Agricultural Handler Exposure Task Force (AHETF) database; and the Outdoor Residential Exposure Task Force (ORETF) database. Some of these data are proprietary (e.g., AHETF data), and subject to the data protection provisions of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).

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1.0 Executive Summary:

This document presents residential exposure/risk assessment for the registered uses of glyphosate.

Use Profile:

Glyphosate (*N*-(phosphonomethyl) glycine) is a nonselective Group 9 herbicide that is currently registered for pre- and post-emergence application to a variety of fruit, vegetable, and field crops. Glyposate is also registered on turf (including golf courses and residential lawns) and on aquatic application.

Exposure Profile

There is a potential for short- and intermediate-term occupational handler exposure to glyphosate during mixing, loading, and applying, and for short- and intermediate-term occupational post-application exposure during post-application activities. Chronic exposure is not expected for the proposed use patterns associated with glyphosate.

Hazard Concerns:

Glyphosate is of low acute toxicity following oral, dermal, and inhalation exposure, since all studies are in Toxicity Category III or IV. It is a mild eye irritant (Toxicity Category III), slight skin irritant (Toxicity Category IV), and is not a dermal sensitizer in guinea pigs. Inhalation and dermal risk assessments (any time period) are not required based on the low toxicity of the formulation products (Toxicity Category III or IV) and the physical characteristics of the technical product (wet cake).

A chronic feeding/carcinogenicity study in rats found no systemic effects in any of the parameters examined (body weight, food consumption, clinical signs, mortality, clinical pathology, organ weights, and histopathology). In a second chronic feeding/carcinogenicity study in rats tested at higher dietary levels, a lowest-observed-adverse-effect level (LOAEL) was identified at 20,000 parts per million (ppm; approximately 940 mg/kg/day) based on decreased body-weight gains in females and increased incidence of cataracts and lens abnormalities, decreased urinary pH, increased absolute liver weight, and increased relative liver weight/brain weight in males. No evidence of carcinogenicity was found in rats. There was also no evidence of carcinogenicity in mice. In a chronic toxicity study in dogs, no systemic effects were found in all examined parameters.

On 26-Jun-1991, the HED Carcinogenicity Peer Review Committee (CPRC) evaluated the weight of the evidence on glyphosate with particular emphasis on its carcinogenic potential. The Committee concluded that glyphosate should be classified as a "Group E" chemical (evidence of non-carcinogenicity for humans), based upon lack of convincing carcinogenicity evidence in adequate studies in two animal species (mice and rats).

Acceptable developmental toxicity studies in the rat and rabbit are available, as is an acceptable 2-generation reproduction study in the rat. No significant reproductive and developmental toxic effects were found. On the basis of developmental studies in rats and rabbits and reproductive findings in rats, glyphosate exhibited no evidence of increased susceptibility of offspring.

Neurotoxicity has not been observed in any of the acute, subchronic, chronic, developmental, or reproductive studies performed with glyphosate.

In the rat metabolism study, absorption was estimated to be 30-36% in males and females following a single 10 mg/kg oral dose. Glyphosate was excreted unchanged in the feces and urine (97.5% minimum). The only metabolite present in the excreta was small amounts of aminomethyl phosphonic acid (AMPA). Less than 1% of the absorbed dose remained in the carcass, primarily the bone. Repeated dosing did not significantly alter metabolism, distribution, and excretion.

Residential Exposure/Risk

Residential exposure to glyphosate may occur as a result of the currently registered turf (including golf courses and residential lawns) and aquatic application scenarios. An updated residential exposure assessment was conducted to reflect HED's 2012 Residential Standard Operating Procedures (SOPs), policy changes for body-weight assumptions, updated POD, and updates to HED's inputs for aquatic/swimmer assessments (Memo, L. Venkateshwara, D398862, 30-Oct-2012).

Based on the registered turf and aquatic use patterns, there is a potential for short-term dermal and inhalation exposure to residential handlers (mixing, loading, and applying) and short-term dermal, inhalation, and incidental oral exposure from post-application activities. Since short-and intermediate-term dermal or inhalation PODs were not selected, a quantitative exposure and risk assessment was not completed for these routes of exposure. However, children may have short-term post-application incidental oral exposures from hand-to-mouth behavior on treated lawns and swimmers (adult and children) may have short-term post-application incidental oral exposures from aquatic uses. HED updated the incidental oral endpoint. The resulting margins of exposure (MOE) do not exceed HED's level of concern (LOC). It is noted that the short-term assessment is protective of intermediate-term exposure as the incidental oral PODs for these durations are identical.

Review of Human Research

This risk assessment relies in part on data from studies in which adult human subjects were intentionally exposed to a pesticide or other chemical. These data, which include the 2012 Residential SOPs (Lawn/Turf), are (1) subject to ethics review pursuant to 40 CFR 26, (2) have received that review, and (3) are compliant with applicable ethics requirements. For certain studies, the ethics review may have included review by the Human Studies Review Board. Descriptions of data sources, as well as guidance on their use, can be found at the Agency website (https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/occupational-pesticide-handler-exposure-data)

2.0 Summary of Conclusions/Data Deficiencies

There are no residential risk estimates of concern associated with the updated incidental oral endpoint.

3.0 Hazard Characterization

Acute Toxicity

Glyphosate is of low acute toxicity following oral, dermal, and inhalation exposure, since all studies are in Toxicity Category III or IV. It is a mild eye irritant (Toxicity Category III), slight skin irritant (Toxicity Category IV), and is not a dermal sensitizer in guinea pigs. Inhalation and dermal risk assessments (any time period) are not required based on the low toxicity of the formulation products (Toxicity Category III or IV) and the physical characteristics of the technical product (wet cake).

A chronic feeding/carcinogenicity study in rats found no systemic effects in any of the parameters examined (body weight, food consumption, clinical signs, mortality, clinical pathology, organ weights, and histopathology). In a second chronic feeding/carcinogenicity study in rats tested at higher dietary levels, a LOAEL was identified at 20,000 parts per million (ppm; approximately 940 mg/kg/day) based on decreased body-weight gain in females and increased incidence of cataracts and lens abnormalities, decreased urinary pH, increased absolute liver weight, and increased relative liver weight/brain weight in males. No evidence of carcinogenicity was found in rats. There was also no evidence of carcinogenicity in mice. In a chronic toxicity study in dogs, no systemic effects were found in all examined parameters.

Neurotoxicity has not been observed in any of the acute, subchronic, chronic, developmental, or reproductive studies performed with glyphosate.

Table 3.1. Acute Toxicity Profile: Glyphosate					
Guideline No.	Study Type	MRID(s)	Results	Toxicity Category	
870.1100	Acute oral	41400601	$LD_{50} > 5,000 \text{ mg/kg}$	IV	
870.1200	Acute dermal	41400602	$LD_{50} > 5,000 \text{ mg/kg}$	IV	
870.1300	Acute inhalation	None	The requirement for an acute inhalation LC ₅₀ study was waived	None	
870.2400	Acute eye irritation	41400603	Corneal opacity or irritation clearing in 7 days or less	III	
870.2500	Acute dermal irritation	41400604	Mild or slight irritant	IV	
870.2600	Skin sensitization	41642307	Not a sensitizer	None	

Table 3.2. Summary of Toxicological Doses and Endpoints for Glyphosate for Use in Human Health Risk Assessments ¹ .					
Exposure/ Scenario	POD	Uncertainty/ FQPA SF	RfD, PAD, LOC	Study and Toxicological Effects	
Acute Dietary (General Population, including Infants and Children)	An endpoint of concern (effect) attributable to a single dose was not identified in the database. Quantification of acute dietary risk to general population including infants and children is not required.				
Chronic Dietary (All Populations)	NOAEL = 100 mg/kg/day	$UF_{A} = 10x$ $UF_{H} = 10x$ $FQPA SF = 1x$	cPAD = cRfD =	Developmental Toxicity Study – Rabbit (MRID 44320616): Maternal LOAEL = 175 mg/kg/day based on dosedependent clinical signs (diarrhea, few and/or no	

Table 3.2. Summary of	Table 3.2. Summary of Toxicological Doses and Endpoints for Glyphosate for Use in Human Health Risk						
Assessments ¹ .	Assessments ¹ .						
Exposure/ Scenario	POD	Uncertainty/ FQPA SF	RfD, PAD, LOC	Study and Toxicological Effects			
				feces). These findings were also seen in another study in rabbits at a similar same dose (MRID 00046362).			
Short- (1-30 days) and Intermediate-(1-6 months) Term Incidental Oral	NOAEL = 100 mg/kg/day	$UF_A = 10x$ $UF_H = 10x$ $FQPA SF = 1x$	LOC (residential) = MOE < 100	Developmental Toxicity Study – Rabbit (MRID 44320616): Maternal LOAEL = 175 mg/kg/day based on dosedependent clinical signs (diarrhea, few and/or no feces). These findings were also seen in another study in rabbits at a similar same dose (MRID 00046362).			
Short- (1-30 days), Intermediate (1-6 months) Term Dermal	ntermediate (1-6 months) A dermal endpoint was not selected; therefore, quantification of dermal risks is not required.						
Short- (1-30 days), Intermediate (1-6 months) Term Inhalation	An inhalation endpoint was not selected, therefore, quantification of inhalation risks is not required.						
Cancer (oral, dermal, inhalation)	Classification	: "Not likely to be	e carcinogenic to hu	mans."			

¹ UF = uncertainty factor, FQPA SF = FQPA Safety Factor, NOAEL = no-observed adverse-effect level, LOAEL = lowest-observed adverse-effect level, PAD = population-adjusted dose (a = acute, c = chronic) RfD = reference dose, MOE = margin of exposure, LOC = level of concern, HDT = highest dose tested, UF_A = extrapolation from animal to human (interspecies), UF_H = potential variation in sensitivity among members of the human population (intraspecies).

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Body Weight

The standard body weight for the general population (80 kg) was used for all exposure scenarios covered in this risk assessment since the endpoints selected were not developmental and/or fetal effects.

4.0 Residential Exposure and Risk Estimates

Glyphosate, a non-selective herbicide, is registered for broadcast and spot treatments on home lawns and gardens. Glyphosate products for homeowner use are packaged as ready-to-mix formulations and ready-to-use sprayers and are common in home and garden stores in the U.S. Glyphosate products are used by lawn care operators (LCOs) for broadcast and spot treatment weed control programs on residential lawns. Glyphosate products are also labeled for turf renovation. Glyphosate is registered for use in recreational areas, including parks and golf courses for control of broadleaf weeds and grasses. Additional registered uses include applications to lakes and ponds, including reservoirs, for non-selective control of nuisance aquatic weeds. These uses were previously assessed in 2012 (Memo, L. Venkateshwara, D398862, 30-Oct-2012), and that assessment reflects HED's 2012 Residential SOPs, policy changes for body-weight assumptions, and updates to HED's inputs for aquatic/swimmer assessments. It should be noted, however, that the MOEs in this document have been updated to reflect a revised POD, the aquatic use scenario has been updated to reflect a higher application rate identified in the JGTF use matrix, and the aquatic scenario inputs have been updated to reflect the draft Aquatic SOP (November, 2015).

4.1 Residential Handler Exposure/Risk Estimates

Based on the registered residential use patterns, there is a potential for short-term dermal and inhalation exposures to homeowners who mix and apply products containing glyphosate (residential handlers). However, since short- and intermediate-term dermal and inhalation PODs were not selected due to the lack of toxicity via these routes, a quantitative exposure risk assessment was not completed.

4.2 Residential Post-application Exposure/Risk Estimates

Post-application dermal and inhalation assessments were not quantitatively assessed since short-and intermediate-term dermal or inhalation PODs were not selected. However, based on the registered use patterns, children may have short-term post-application incidental oral exposures from hand-to-mouth behavior on treated lawns and swimmers (adults and children) may have short-term post-application incidental oral exposures from the aquatic use. It is noted that the short-term assessment is protective of intermediate-term exposure as the incidental oral PODs for these durations are identical.

Glyphosate is used in many areas that can be frequented by the general population including residential areas (e.g., home lawns). It is also registered for use in lakes and ponds, including reservoirs, for control of nuisance aquatic weeds. As a result, individuals can be exposed by entering these areas if they have been previously treated. Post-application dermal and inhalation assessments were not quantitatively assessed since short- and intermediate-term dermal or inhalation endpoints were not selected. However, based on the registered use patterns, child 1<2 may have short-term post-application incidental oral exposures from hand-to-mouth behavior on treated lawns and swimmers (adult and child 3<6) may have short-term post-application incidental oral exposures from aquatic uses.

Table 4.2.1 presents the post-application incidental oral MOE values calculated for children 1 to <2 years old after applications of glyphosate to turf. Table 4.2.2 presents the post-application incidental oral ingestion MOE values calculated for adults and children 3 to <6 years old after aquatic applications of glyphosate. The post-application MOEs do not exceed the LOC for any of the scenarios assessed (LOC for MOEs <100). It is noted that the lifestages selected for risk assessment are considered protective for the exposures and risks for any other potentially exposed lifestages.

The incidental oral scenarios for the turf assessment (i.e., hand-to-mouth, object-to-mouth, and soil ingestion) should be considered inter-related and it is likely that they occur interspersed amongst each other across time. Combining these scenarios would be overly-conservative because of the conservative nature of each individual assessment. Therefore, none of the incidental oral scenarios were combined.

Table 4.2.1. Post-application Incidental Oral Risk Estimates for Application of Glyphosate to Turf ¹ .					
Lifestage Post-application Exposure Scenario Exposure (mg/kg/day) Short-term MOEs ⁵					
		Hand-to-Mouth ²	0.1565	640	
Children 1 to <2 year old	Turf – sprays	Object-to-Mouth ³	0.00481	21,000	
		Incidental Soil Ingestion ⁴	0.00034	290,000	

¹ Based on the maximum labeled rate specified in the Roundup® Weed & Grass Super Concentrate, EPA Reg. No. 71995-25.

³ Object-to-Mouth = ((Object Residue (μg/cm²)*CF1 (1.0E-3 mg/μg)*Object Surface Area Mouthed/Event (10 cm²/event))*(Exposure Time (1.5 hrs/day)*#Replenishment Intervals/hr (4))*(1-((1-Extraction by Saliva (0.48))^(#Object-to-Mouth Events/hr (8.8 events/hr)/#Replenishment intervals/hr))))/Body Weight (11 kg).

⁴ Soil Ingestion = (Soil Residue (7.0746975 μ g/g) *Ingestion Rate (50 mg/kg/day) *CF(0.000001))/Body Weight (11 kg).

⁵ MOE = NOAEL/Daily Dose (mg ae kg/day); Oral NOAEL = 100 mg/kg/day. LOC is for MOEs <100.

Table 4.2.2. Post-Application Swimmer Risk Estimates for Aquatic Application of Glyphosate.						
Exposure Scenario	Application Rate (lb ae/acre) ¹	Maximum Concentration in water (mg/L) ²	Exposure (mg/kg/day) ³	Short-term MOE ⁴		
Ingestion of water, Adult	0	(&)	0.000046035	2,200,000		
Ingestion of water, Children 3 to <6 years old	8	0.737	0.000484583	210,000		

¹ Application rate from registered labels for aquatic weed control using glyphosate IPA salt (label = EPA Reg. No. 524-343 identified in the JGTF Use Matrix as the highest aquatic rate). Note this rate is higher than previously assessed in D398862.

Table 4.3 reflects the residential risk estimates that are recommended for use in the aggregate assessment. The recommended residential exposure scenario for use in the adult aggregate assessment reflects short-term incidental oral exposure to treated aquatic areas (post-application exposure). The recommended residential exposure scenario for use in the child aggregate assessment reflects short-term incidental oral exposure to children 1 to <2 years old from treated turf (post-application exposure). As indicated above, the short-term assessment is protective of intermediate-term exposure (identical incidental oral POD for these durations) and the lifestages selected for aggregate risk assessment are considered protective for the exposures and risks for any other potentially exposed lifestage.

Table 4.3. Recommendations for the Residential Exposures for the Glyphosate Aggregate Assessment.							
Lifestage	Expo	posure (mg/kg/day) ¹		Total Exposure (mg/kg/day)	MOE ²		
Lifestage	Dermal	Inhalation	Oral	Total Exposure (mg/kg/day)	MIOE-		
short-term	short-term						
Adults not applicable 0.00			0.000046035	0.000046035	2,200,000		
Children 1 to <2 year old	not applicable		0.1565	0.1565	640		

Post-application exposure represents high-end incidental oral exposure for the relevant exposure duration.

4.3 Non-Occupational Bystander Post-Application Inhalation Exposure and Risk Estimates

Volatilization of pesticides may be a source of post-application inhalation exposure to individuals nearby pesticide applications. The Agency sought expert advice and input on issues related to volatilization of pesticides from its FIFRA SAP in December 2009, and received the SAP's final report on March 2, 2010 (http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPP-2009-0687-0037). The Agency has evaluated the SAP report and has developed a Volatilization Screening Tool and a subsequent Volatilization Screening Analysis (http://www.regulations.gov/#!docketDetail;D=EPA-HQ-OPP-2014-0219).

² Hand-to-Mouth = Hand residue loading (mg/cm²)*fraction hand surface area mouthed/event (0.127/event)*typical surface area of one hand (150 cm²)*exposure time (1.5 hrs/day)*number of replenishment intervals/hr (4 intervals/hr)*(1-(1-saliva extraction factor (0.5)^number of hand-to-mouth contact events per hour (13.9 events/hr); *Hand Residue Loading* = fraction of ae on hands compared to total surface residue from dermal TC study (0.06)*dermal exposure (mg))/typical surface area of one hand (150 cm²).

² Maximum concentration in water (top 4 ft) = 8 lb ae/acre x 1A/43,560 ft² x 454,000 mg/lb x 4ft x ft³/28.32 L = 0.737 mg/L.

³ PDR, incidental oral exposure = concentration, C_w (mg/L) x ingestion rate, IgR (L/hr) x exposure time, ET (hrs/d) x 1/BW (adult = 80 kg; children (3 to <6 years old) = 19 kg).

⁴ MOE = NOAEL/PDR; short-term incidental oral NOAEL = 100 mg/kg bw/d. LOC is for MOEs <100.

² Residential post-application MOE = Incidental oral NOAEL / Residential post-application total exposure; LOC for MOEs <100.

During Registration Review, the Agency will utilize this analysis to determine if data (i.e., flux studies, route-specific inhalation toxicological studies) or further analysis is required for glyphosate.

4.4 Non-Occupational Spray Drift Exposure and Risk Estimates

Off-target movement of pesticides can occur via many types of pathways and it is governed by a variety of factors. Sprays that are released and do not deposit in the application area end up off-target and can lead to exposures to those it may directly contact. They can also deposit on surfaces where contact with residues can eventually lead to indirect exposures (e.g., children playing on lawns where residues have deposited next to treated fields). The potential risk estimates from these residues can be calculated using drift modeling coupled with methods employed for residential risk assessments for turf products.

The approach to be used for quantitatively incorporating spray drift into risk assessment is based on a premise of compliant applications which, by definition, should not result in direct exposures to individuals because of existing label language and other regulatory requirements intended to prevent them.¹ Direct exposures would include inhalation of the spray plume or being sprayed directly. Rather, the exposures addressed here are thought to occur indirectly through contact with impacted areas, such as residential lawns, when compliant applications are conducted. Given this premise, exposures for children (1 to 2 years old) and adults who have contact with turf where residues are assumed to have deposited via spray drift thus resulting in an indirect exposure are the focus of this analysis analogous to how exposures to turf products are considered in risk assessment.

Several glyphosate products have existing labels for use on turf, thus it was considered whether the risk assessment for that use would be considered protective of any type of exposure that would be associated with spray drift. If the maximum application rate on crops adjusted by the amount of drift expected is less than or equal to existing turf application rates, the existing turf assessment is considered protective of spray drift exposure. The currently registered maximum single agricultural application rate of glyphosate for several scenarios is at 8.0 lb ae/acre (grass pastures, forestry, and Christmas tree farms). The highest fraction of spray drift noted for any application method immediately adjacent to a treated field results in a deposition fraction of 0.26² of the application rate. A quantitative spray drift assessment for glyphosate is not required because the maximum application rate for the relevant uses multiplied by the 0.26x adjustment factor for drift (8.0 lb ae/acre x 0.26 = 2.08 lb ae/acre) is less than the assessed maximum direct spray residential turf application rate (10.5 lb ae/acre; D398862, L. Venkateshwara, 30-Oct-2012). As a result, the turf post-application assessment is protective for any potential exposures for any glyphosate products. The turf post-application MOEs have been previously assessed and are based on the revised SOPs for Residential Exposure Assessment (i.e., see above in Section 4.2).

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¹ This approach is consistent with the requirements of the EPA's Worker Protection Standard which, when included on all labels, precludes direct exposure pathways.

² Tier 1 output from the aerial application using fine to medium spray quality based on AgDrift® output files

Appendix A. Summary of Residential Post-application Algorithms

1.0 Residential Post-application

1.1 Turf/Physical Activities on Turf

Post-application Dermal Exposure Algorithm – Physical Activities on Turf

Exposure resulting from contacting previously treated turf while performing physical activities is calculated as shown below. Residential post-application exposure assessment must include calculation of exposure on the day of application. Therefore, though an assessment can present exposures for any day "t" following the application, it must include "day 0" exposure.

$$E = TTRt * CF1 * TC * ET$$

where:

E = exposure (mg/day);

TTRt = turf transferable residue on day t (μ g/cm²);

CF1 = weight unit conversion factor (0.001 mg/ μ g);

TC = transfer coefficient (cm²/hr); and

ET = exposure time (hr/day).

If chemical-specific TTR data are available, then surface residues from the day of application should be used (assume that individuals could be exposed to residues immediately after application). However, if data are not available, then TTR_t can be calculated using the following formula:

$$TTR_t = AR * F * (1-FD)_t * CF2 * CF3$$

where:

TTRt = turf transferable residue on day t (μ g/cm²);

 $AR = application rate (lbs ai/ft^2 or lb ai/acre);$

F = fraction of ai as transferable residue following application (unitless);

FD = fraction of residue that dissipates daily (unitless);

t = post-application day on which exposure is being assessed;

CF2 = weight unit conversion factor (4.54 x 10^8 µg/lb); and

CF3 = area unit conversion factor $(1.08 \times 10^{-3} \text{ ft}^2/\text{ cm}^2 \text{ or } 2.47 \times 10^{-8} \text{ acre/cm}^2)$.

Dermal absorbed doses are calculated as:

$$D = \frac{E * AF}{BW}$$

where:

D = dose (mg/kg-day);

E = exposure (mg/day);

AF = absorption factor (dermal); and

BW = body weight (kg).

Table A-1: Turf (Physical Activities) Inputs for Residential Post-application Dermal Exposure				
Algorithm Notation	Exposure Factor (units)			Point Estimate(s)
AR	(m		ation rate dient per unit area)	10.5
	Fraction of	AR as TTR	L/WP/WDG	0.01
F	following application (if chemical-specific data is unavailable)		Granules	0.002
	Daily residu	ue dissipation	L/WP/WDG	0.1
F_D	(if chemical-specific data is unavailable) (fraction)		Granules	0.1
		L/WP/WDG	Adults	180,000
TC	Transfer	L/WP/WDG	Children 1 < 2 years old	49,000
TC	Coefficient (cm ² /hr)	Granules	Adults	200,000
	(em /m)	Granules	Children 1 < 2 years old	54,000
ET	Exposi	ire Time	Adults	1.5
EI	(hours	per day)	Children 1 < 2 years old	1.5
BW	Body	Weight	Adults	80
		kg)	Children $1 < 2$ years old	11
L/WP/WDG = Liquids/Wet	ttable Powders	s/Water-dispersi	ble Granules	

<u>Post-application Hand-to-Mouth Exposure Algorithm – Physical Activities on Turf</u> Exposure from hand-to-mouth activity is calculated as follows (based on the algorithm utilized in the SHEDS-Multimedia model):

$$E = [HR * (F_M * SA_H) * (ET * N_Replen) * (1 - (1 - SE)^{(Freq_HtM/N-Replen)})]$$

where:

E = exposure (mg/day);

 $HR = \text{hand residue loading (mg/cm}^2);$

FM = fraction hand surface area mouthed / event (fraction/event);

SAH = typical surface area of one hand (cm²);

ET = exposure time (hr/day);

N Replen = number of replenishment intervals per hour (intervals/hour);

SE = saliva extraction factor (i.e., mouthing removal efficiency); and

Freq_HtM = number of hand-to-mouth contacts events per hour (events/hour).

and

$$HR = \frac{Fai_{hands} * DE}{SA_{H} * 2}$$

where:

 $HR = \text{hand residue loading (mg/cm}^2);$

Fai_{hands} = fraction ai on hands compared to total surface residue from dermal transfer coefficient study (unitless);

DE = dermal exposure (mg); and

 SA_H = typical surface area of one hand (cm²).

Dose, normalized to body weight, is calculated as:

$$D = \frac{E}{BW}$$

where:

D = dose (mg/kg-day);

E = exposure (mg/day); and

BW = body weight (kg).

Table A-2: Turf (Physical Activities) – Inputs for Residential Post-application Hand-to-Mouth Exposure				
Algorithm Notation	Exposure (uni		Point Estimate(s)	
Fai_{hands}	Fraction of ai on hands from dermal transfer	Liquid formulations	0.06	
1 alhands	coefficient study (unitless)	Granular formulations	0.027	
DE	Dermal exp	osure (mg)	Calculated	
SA_{H}	Typical surface area of one 2 year		150	
AR	Applicat (mass active ingred		10.5	
HR	Residue available on	the hands (mg/cm ²)	Calculated via (DE * Fai _{hands})/SA _H	
F _M	Fraction hand surfaction (fraction		0.127	
N_Replen	Replenishment in (interva		4	
ET	Exposure time (hrs/day)		1.5	
SE	Saliva extrac (unitl		0.48	
Freq_HtM	Hand-to-mouth events per hour (events/hr)		13.9	
BW	Body Weight (kg)	Children 1 < 2 years old	11	

Post-application Object-to-Mouth Exposure Algorithm - Physical Activities on Turf

Exposure from object-to-mouth activity is calculated as follows (based on the algorithm utilized in SHEDS-Multimedia):

$$E = [OR*CF1*SAM_O*(ET*N_Replen)*(1-(1-SE_O)^{(Freq_OtM/N_Replen)})]$$

where:

E = exposure (mg/day);

OR = chemical residue loading on the object on day "t" (ug/cm²);

CF1 = weight unit conversion factor (0.001 mg/ μ g);

 $SAM_O = area of the object surface that is mouthed (cm²/event);$

ET = exposure time (hr/day);

N_Replen = number of replenishment intervals per hour (intervals/hour);

SE_O = saliva extraction factor (i.e., mouthing removal efficiency); and

Freq_OtM = number of object-to-mouth contact events per hour (events/hour).

and

$$OR = AR * F_O * CF2 * CF3$$

where:

OR = chemical residue loading on the object ($\mu g/cm^2$);

 $AR = application rate (lbs ai/ft^2 or lb ai/acre);$

 F_0 = fraction of residue available on the object (unitless);

CF2 = weight unit conversion factor (4.54 x $10^8 \mu g/lb$); and

CF3 = area unit conversion factor $(1.08 \times 10^{-3} \text{ ft}^2/\text{cm}^2 \text{ or } 2.47 \times 10^{-8} \text{ acre/cm}^2)$.

Dose, normalized to body weight, is calculated as:

$$D = \frac{E}{BW}$$

where:

D = dose(mg/kg-day);

E = exposure (mg/day); and

BW = body weight (kg).

Table A-3: Turf (Physical Activities) – Inputs for Residential Post-application Object-to-Mouth Exposure				
Algorithm Notation	Exposure Factor (units)	Point Estimate(s)		
AR	Application rate (to turf) (mass active ingredient per unit area)	10.5		
Fo	Fraction of AR as OR following application ¹	0.01		
SAMo	Surface area of object mouthed (cm²/event)	10		

Table A-3: Tu Exposure	Table A-3: Turf (Physical Activities) – Inputs for Residential Post-application Object-to-Mouth Exposure				
Algorithm Notation	•	sure Factor (units)	Point Estimate(s)		
N_Replen	Replenishment interv	vals per hour (intervals/hour)	4		
SEo		xtraction factor fraction)	0.48		
ET	Exposure time (hours per day)		1.5		
Freq_OtM	Object-to-mouth events per hour (events/hr)		8.8		
BW	Body Weight (kg) Children 1 < 2 years old		11		
1 551 1 0 0 7	1 11 01 11	1 0 111 0			

¹ This SOP assumes that all of the residue on the turf could be transferred to the object (e.g., object residue is equal to turf transferable residue).

<u>Post-application Incidental Soil Ingestion Exposure Algorithm— Physical Activities on Turf</u> Exposure from incidental soil ingestion is calculated as follows:

$$E = SRt * SIgR * CF1$$

where:

E = exposure (mg/day);

SRt = soil residue on day "t" (µg/g);

SIgR = ingestion rate of soil (mg/day); and

CF1 = weight unit conversion factor (1 x 10^{-6} g/µg).

and

$$SRt = AR * FS * (1-F_D)^t * CF2 * CF3 * CF4$$

where:

 $SR_t = soil residue on day "t" (\mu g/g);$

 $AR = application rate (lbs ai/ft^2 or lb ai/acre);$

FS = fraction of ai available in uppermost cm of soil (fraction/cm);

 F_D = fraction of residue that dissipates daily (unitless);

T = post-application day on which exposure is being assessed;

CF2 = weight unit conversion factor (4.54 x $10^8 \,\mu g/lb$);

CF3 = area unit conversion factor $(1.08 \times 10^{-3} \text{ ft}^2/\text{cm}^2 \text{ or } 2.47 \times 10^{-8} \text{ acre/cm}^2)$; and

CF4 = soil volume to weight unit conversion factor (0.67 cm³/g soil).

Dose, normalized to body weight, are calculated as:

$$D = \frac{E}{BW}$$

where:

D = dose (mg/kg-day);

E = exposure (mg/day); and

BW = body weight (kg).

Table A-4: Turf (Physical Activities) – Inputs for Residential Post-application Incidental Soil Ingestion Exposure						
Algorithm Notation	Exp	osure Factor (units)	Point Estimate(s)			
AR		olication rate ngredient per unit area)	10.5			
FS		able in uppermost 1 cm of soil (unitless)	1			
F_D	1	sidue dissipation (fraction)	0.1			
SIgR	Soil inges	ation rate (mg/day)	50			
BW	Body weight (kg)	Children 1 < 2 years old	11			

2.0 Aquatic Use

This SOP provides a standard method for estimating the dose for adults and children 3 < 6 years old from incidental ingestion of water from treated aquatic areas (e.g., lakes). This scenario assumes that swimmers ingest water that enters their mouth during swimming or playing in the treated water.

Post-application Incidental Ingestion Exposure Algorithm

Exposure from incidental ingestion of treated water is calculated as follows:

$$E = C_w * IgR * ET$$

Where:

E = exposure (mg/day),

 C_w = chemical concentration in water (mg/L),

IgR = ingestion rate of water (L/hr),

ET = exposure time (hrs/day).

Dose, normalized to body weight, is calculated as:

$$D = \frac{E}{BW}$$

where:

D = dose (mg/kg-day); E = exposure (mg/day); BW = body weight (kg).

Post-application incidental ingestion following aquatic applications is generally considered short-term in duration. Refinement of this dose estimate to reflect a more accurate short-term

multi-day exposure profile can be accomplished by accounting for the various factors outlined in *Sections 1.3.2* and *1.3.4*, such as residue dissipation, product-specific re-treatment intervals, and activity patterns. If longer-term assessments (i.e., intermediate-, long-term, or lifetime exposures) are deemed necessary, similar refinements to more accurately reflect the exposure profile are recommended.

Post-application Incidental Ingestion Exposure Algorithm Inputs and AssumptionsRecommended values for post-application incidental ingestion exposure assessments are provided in **Error! Reference source not found.** below. Following this table, each scenario-specific input parameter is described in more detail. This description includes a summary of i) key assumptions; ii) data sources used to derive recommended input values; and iii) discussion of limitations that should be addressed when characterizing exposure.

Table XX: Aquatic Applications – Recommended Point Estimates for Post-Application Incidental Ingestion Exposure Factors.			
Algorithm Notation	Exposure Factor (units)		Point Estimate(s)
$C_{\rm w}$	Chemical concentration in water (mg/L)		Based on either (1) monitoring data or (2) label information
IgR	Ingestion rate (L/hr)		0.05
ET	Exposure Time (hours per day)	Adults	0.1
		Children 3 < 6 years old	0.25
BW	Body weight (kg)	Adults	80
		Children 3 < 6 years old	19

Chemical concentration in water (C_w)

The chemical concentration is water can be estimated based on (1) chemical-specific monitoring data or (2) the application rate provided on the product label. If the application rate provided on the label is only given in lb active ingredient (ai) per area (rather than lb ai/volume), then an assumption of 4 feet depth (and uniform distribution) can be used to estimate the concentration in water.

Ingestion rate of water (IgR)

Water ingestion rates are based on the Risk Assessment Guidance for Superfund (RAGS) Part A (http://www2.epa.gov/risk/risk-assessment-guidance-superfund-rags-part) which references a value from the Superfund Exposure Assessment Manual (USEPA, 1988). The recommended point estimate for use in post-application incidental ingestion exposure assessments is 0.05 L/hr of swimming for adults and children 3 < 6 years old.

Exposure Time

The exposure time for swimming in aquatic areas is based on information provided in the 2011 Exposure Factors Handbook (USEPA, 2011). Data are provided on the number of minutes per month spent swimming in a freshwater swimming pool (Tables 16-40 and 16-42). Using these data, monthly averages were calculated and the recommended point estimates for use in post-application inhalation exposure assessments are 0.1 hour/day for adults and 0.25 hour/day for children 3 < 6 years old.

Future Research/Data Needs

Unavailable information that would refine post-application ingestion exposure assessments for pesticide applications to aquatic areas include:

- Application intervals (i.e., how often chemicals are applied to aquatic areas) either chemical-specific or generic information.
- Survey information (preferably longitudinal) detailing:
 - o Daily/weekly/monthly probability of treating aquatic areas with pesticides;
 - Product-specific application rates to obtain the likelihood that the maximum rate is used; and,
 - o Daily activity patterns specific to aquatic areas.
- Post-application exposure data, specifically for residential aquatic area activities, and/or describing the extent to which an individual's exposure for a given activity varies.

Exposure Characterization and Data Quality

• The exposure time for swimming is based on the average time spent in a freshwater swimming pool, and is used as a surrogate for lakes/ponds.

Combining Post-application Scenarios

Risks resulting from different exposure scenarios are combined when it is likely that they can occur simultaneously based on the use pattern and when the toxicological effects across different routes of exposure are the same. When combining scenarios, it is important to fully characterize the potential for co-occurrence as well as characterizing the risk inputs and estimates. Risks should be combined even if any one scenario or route of exposure exceeds the level of concern because this allows for better risk characterization for risk managers. For the aquatic areas scenario, dermal, inhalation and incidental ingestion exposures can be combined if the routes share a common toxicological endpoint.